SECTION 5 - 510(K) SUMMARY

EV1000 CLINICAL PLATFORM 510(k) SUMMARY	
510(k) Submitter	Edwards Lifesciences
Contact Person	Sally L. Maher One Edwards Way Irvine, CA 92614-5686
Date Prepared	May 16, 2014
Trade Name	EV1000 Clinical Platform
Common Name	Cardiac Output/Oximetry Computer
Classification Name	Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435, product code DXG)
Regulation Class/ Product Code	Class II/ DXG, DQE
Predicate Device	EV1000 Clinical Platform, K110597 (cleared 14 June 2011)
Device Description	The EV1000 Clinical Platform consists of Databox and Monitor components, which can be mounted to an IV pole. The EV1000 Clinical Platform measures patient physiologic parameters when it is used as a system with various Edwards components, including the Edwards pressure transducers, the FloTrac sensor, the components of the VolumeView System, oximetry catheters/sensors, and the corresponding accessories applied to the patient. The EV1000 Databox receives incoming signals from the patient through the connections provided by the accessories applied to the patient. The algorithms embedded in the Databox process the signals and provide parameter calculations. The EV1000 Monitor is connected to the Databox via an ethernet cable. The Monitor is a touchscreen, panel PC with a graphical user interface (GUI). The Monitor displays the measured and calculated parameter values from the Databox. The EV1000 Clinical Platform, when used with the VolumeView System, measures and/or calculates hemodynamic parameters such as: • Manual-calibrated continuous parameters: cardiac output, cardiac index, stroke volume, stroke volume index, systemic vascular resistance, systemic vascular resistance index, and stroke volume variation; and,

EV1000 CLINICAL PLATFORM 510(k) SUMMARY	
Device Description, Continued	• Manual-calibrated intermittent parameters: cardiac output , cardiac index, extravascular lung water, extravascular lung water index, global ejection fraction, global end-diastolic volume, global end-diastolic volume index, intrathoracic blood volume, pulmonary vascular permeability index, stroke volume, stroke volume index, systemic vascular resistance, and systemic vascular resistance index. When connected to a FloTrac sensor, the EV1000 Clinical Platform continuously measures/calculates auto-calibrated arterial pressure cardiac output, cardiac index, stroke volume, stroke volume index, stroke volume variation, systemic vascular resistance, and systemic vascular resistance index. When connected to Edwards oximetry sensors, the EV1000 Clinical Platform continuously measures/calculates oximetry parameters (specifically mixed venous oximetry (SvO2) and central venous oximetry (ScvO2).
Indications for Use/ Intended Use	The EV1000 Clinical Platform is indicated for use primarily for critical care patients in which the balance between cardiac function, fluid status and vascular resistance needs continuous or intermittent assessment. Analysis of the thermodilution curve in terms of mean transit time and the shape is used to determine intravascular and extravascular fluid volumes. When connected to an Edwards oximetry catheter, the monitor measures oximetry in adults and pediatrics. The EV1000 Clinical Platform may be used in all settings in which critical care is provided.
Comparative Analysis	Verification and validation testing was conducted to compare the performance and functionality of the EV1000 Clinical Platform to the predicate device. This testing regimen included side-by-side bench and pre-clinical studies, and comparative analysis of clinical data. The EV1000 Clinical Platform has been shown to be safe, effective, and substantially equivalent to the cited predicate device for its intended use in critical care environments.
Functional/ Safety Testing	The EV1000 Clinical Platform has successfully passed functional and performance testing, including software verification and validation, mechanical and electrical testing, bench studies, pre-clinical animal studies, comparison testing of clinical cases, and clinical utility.
Conclusion	The EV1000 Clinical Platform has been shown to be safe, effective, and is substantially equivalent to the cited predicate device for its intended use in critical care environments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 22, 2014

Edwards Lifesciences LLC
Mr. Stephen M. Enos
Director, Regulatory Affairs
One Edwards Way
Irvine, CA 92614

Re: K131892
Trade Name: Edwards Lifesciences™ EV1000 Clinical Platform, Model EV 1000A
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DXG
Dated: May 6, 2014
Received: May 7, 2014

Dear Mr. Enos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

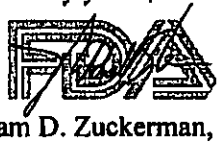
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131892

Device Name

Edwards Lifesciences™ EV1000™ Clinical Platform

Indications for Use *(Describe)*

The EV1000 Clinical Platform is indicated for use primarily for critical care patients in which the balance between cardiac function, fluid status and vascular resistance needs continuous or intermittent assessment. Analysis of the thermodilution curve in terms of mean transit time and the shape is used to determine intravascular and extravascular fluid volumes. When connected to an Edwards oximetry catheter, the monitor measures oximetry in adults and pediatrics. The EV1000 Clinical Platform may be used in all settings in which critical care is provided.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA Date: 2014.05.22 11:25:37 -04'00'

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